UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE CORMEDIX INC. SECURITIES LITIGATION	Civil Action No. 2:21-cv-14020-JXN-CLW CLASS ACTION Motion Day: September 3, 2024
This Document Relates To: ALL ACTIONS	ORAL ARGUMENT REQUESTED

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE THIRD AMENDED CONSOLIDATED CLASS ACTION COMPLAINT

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INTRODUCTION

This is a class action lawsuit that seeks to turn setbacks in the U.S. Food and Drug Administration ("FDA") approval process into a securities fraud. What is missing, however, is the fraud. Fatally absent from the Third Amended Complaint[1] are allegations that the Defendants knew specific facts—such as concerns raised by FDA, deficiencies in the New Drug Application ("NDA"), or other red flags about the status of the NDA—that contradicted their public statements to investors during the Class Period.[2] Hence, this is precisely the kind of "fraud by hindsight" pleading the Private Securities Litigation Reform Act of 1995 (the "PSLRA") was designed to prevent. The TAC should be dismissed with prejudice.

This case centers on CorMedix (the "Company"), a biopharmaceutical company, based in Berkley Heights, New Jersey, that focuses on developing and commercializing therapeutic products for the prevention and treatment of infectious and inflammatory diseases. ¶ 47. During the Class Period, its lead product candidate was DefenCath (previously known as Neutrolin), a first-in-class drug product designed to reduce the incidence of catheter-related bloodstream infections. *See* ¶ 2.

On July 8, 2020, in the midst of the COVID-19 pandemic, CorMedix completed its DefenCath NDA submission. ¶ 98. On March 1, 2021, CorMedix announced that it had received a Complete Response Letter ("CRL") indicating that the NDA could not be approved at that time. The CRL—appended to the TAC—provided two bases for the decision. First, after CorMedix submitted the NDA, FDA, which was unable to perform a pre-approval inspection due to the pandemic, requested records from CorMedix's independent contract manufacturing organization

[1] Third Amended Class Action Complaint (ECF No. 97) (the "TAC"). Unless otherwise noted, all citations to "¶ __" refer to the TAC.

[2] "Class Period" is defined as October 16, 2019 through August 8, 2022, inclusive. TAC at 1.

("CMO"), and thereafter noted objectionable conditions at the CMO based on a review of those records. Second, FDA directed CorMedix to perform an "extraction study" to demonstrate that the labeled volume of product could be consistently withdrawn from vials. TAC Ex. 2, at 8–9. The CMO had recently been hired as the "fill-finish" site for Moderna's COVID-19 vaccine and FDA noted deficiencies relating to new equipment being installed for the vaccine. ¶¶ 163–64, 223.

On February 28, 2022, CorMedix announced it had resubmitted the NDA and the CMO had submitted responses to FDA. ¶ 144. On August 8, 2022, FDA issued a second CRL. ¶ 157. The second CRL—likewise appended to the TAC—noted that the NDA could not be approved based on observations obtained during the first FDA inspection of the CMO, as well as a "recent" inspection of a key ingredient supplier. ¶ 281. Again, the issues noted by FDA had little to do with CorMedix, the NDA, or, for that matter, any failure to remediate the issues in the First CRL. Instead, FDA had recently issued "inspectional observations" to the CMO on "Form 483." ¶¶ 171–72. And the active pharmaceutical ingredient ("API") manufacturer received a warning letter from FDA for an ingredient *not* used in DefenCath and with equipment and facilities distinct from those used in the manufacture of DefenCath's API. ¶ 281. Nevertheless, these issues delayed approval of DefenCath.

From this chronology, Plaintiff infers a sprawling, nearly three-year long fraud on investors. Of course, Plaintiff conspicuously omits that, following the Class Period, DefenCath *was approved* by FDA. But the TAC fails at a more fundamental level. Plaintiff simply assumes that the outcome—a delayed approval caused by difficulties at third-party manufacturers and suppliers during a pandemic—must have been preordained and known to Defendants all along, but Plaintiff fails to plead any particularized facts supporting his theory, let alone any hallmarks of fraud.

Little has changed since the Second Amended Complaint.[3] Notably, Plaintiff abandoned his claims under the Securities Act of 1933 (the "Securities Act"). As to his remaining claims under the Securities Exchange Act of 1934 (the "Exchange Act"), Plaintiff failed to cure any pleading defects. At most, Plaintiff added certain allegations attributed to an unnamed witness who claims a pre-Class Period audit by an outside consultant concluded that the CMO would never be able to pass an FDA inspection. ¶¶ 80–87. But this claim is not based on personal knowledge, lacks key detail about what the audit found and how that relates, if at all, to the CRLs, and lacks corroboration from the *consultant*, who is purportedly the first cooperating witness. As such, it need not be credited, and it fails to contradict anything Defendants said during the Class Period.

The TAC still fails to meet any of the required elements of a securities fraud claim.

No Scienter. Plaintiff fails to plead facts supporting the "compelling" inference of scienter required by the PSLRA. Plaintiff pleads no motive to commit securities fraud. Indeed, Company insiders ***purchased*** CorMedix stock during the Class Period. Nor does Plaintiff plead what facts Defendants knew that contradicted their public statements. Taking the allegations as a whole, the much more compelling inference is that Defendants believed the NDA would be approved, frequently updated (and warned) investors regarding the status of the NDA as new facts emerged, and tried in good faith to remediate difficult manufacturing and supply issues during the pandemic, rather than Plaintiff's theory that they gambled on a fatally flawed NDA, one ultimately approved, no less. *See Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308 (2007).

No False Statements. Over 140 pages, 325 paragraphs, Plaintiff alleges that Defendants made over 50 false statements. Yet none is pled with the particularity required by the PSLRA.[4]

[3] Second Amended Consolidated Class Action Complaint (ECF No. 79) (the "SAC").

[4] Summary charts are included in appendices as to each category of alleged misstatement.

- Truthful Statements About the NDA: Plaintiff challenges a wide range of Defendants' statements about various FDA touchpoints, such as that no further CMC meetings with FDA are planned, CorMedix has completed its NDA submission, or CorMedix is working closely with the CMO to remediate the deficiencies in the CRL. However, no facts are pled supporting any of these statements were false when made or put "in play" the ultimate approval of the NDA. *See* Apps. A–B.

- Forward-Looking Statements Protected by Safe Harbor: Much of the TAC is devoted to challenging Defendants' forward-looking statements, such as the anticipated date FDA would issue a decision on the NDA, statements the Company was "on schedule" with its submission, and statements about the timeline for resubmitting the NDA. But these statements are protected by the PSLRA's "Safe Harbor" because all were accompanied by meaningful cautionary language. *See* App. C.

- Inactionable Statements of Optimism or Opinion: The TAC cites various statements of corporate optimism, such as having an "experienced and competent" team and Defendants' belief they had "adequately addressed the concerns identified by the FDA." However, these statements are either wholesale inactionable under the securities law and/or the TAC lacks allegations that they were actually disbelieved by the speaker or mischaracterized the basis of the opinion. *See* App. D.

No Loss Causation. The TAC fails for an independent reason: Plaintiff fails to allege the disclosure of any fraudulent scheme. That is to say, none of the "corrective disclosures" pled—instances in which Defendants provided regulatory updates concerning DefenCath—are actually "corrective" of any prior statements. Instead, they all represent instances in which Defendants disclosed *new information* to the market. But as the Supreme Court has made clear, that is insufficient to allege securities fraud. *See Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 339 (2005).

Defendants respectfully submit that it is time to bring this lawsuit, pending since 2021, to its end. That Plaintiff cannot plead fraud after three attempts underscores there was no fraud here. Any further amendment would be futile. The TAC should be dismissed with prejudice.

FACTUAL BACKGROUND

DefenCath. DefenCath is an antimicrobial catheter lock solution—a solution placed into catheters to fill the catheter when not in use—designed to prevent life-threatening catheter-related

bloodstream infections ("CRBSIs"). ¶ 2.[5] CRBSIs can result in significant morbidity, increased rates of hospital admissions, readmissions, and death. *See* Ex. A at 1. CorMedix previously sold DefenCath in Europe from 2013 to 2022 under the name "Neutrolin." ¶ 6. In November 2023, DefenCath was approved by FDA to reduce the incidence of CRBSIs in adult patients with kidney failure receiving chronic hemodialysis through a central venous catheter.[6] Ex. B.

Individual Defendants. The "Individual Defendants" held or hold the following positions: Khoso Baluch (Chief Executive Officer and Director from October 2016 until October 2021); Robert Cook (Chief Financial Officer from February 1, 2017–January 31, 2020); Matthew David (Chief Financial Officer and Executive Vice President since May 2020); John Armstrong (Executive Vice President for Technical Operations from March 2017 until October 2021); Joseph Todisco (Chief Executive Officer since May 10, 2022); Phoebe Mounts (Executive Vice President, General Counsel, and Secretary from March 2019 until December 2023). ¶¶ 48–55.

CorMedix's CMO. CorMedix does not manufacture DefenCath in its own facilities; rather, it partners with third-party CMOs skilled in the production of pharmaceutical products. ¶ 79. In 2017, after evaluating over a dozen potential CMOs, CorMedix selected ROVI Contract Manufacturing, S.L. ("ROVI"), located in Spain. ¶¶ 4, 79. ROVI supplies pharmaceuticals to more than 60 countries and, at the time, had passed numerous inspections from health regulators

[5] This Court may consider the following on this motion: (i) the TAC and documents referenced therein, (ii) SEC filings, and (iii) public information capable of judicial notice, such as stock prices or FDA guidance. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007) (court "must consider" documents "incorporated . . . by reference" and matters subject to judicial notice); *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1331 (3d Cir. 2002). The Declaration of David A. Kotler accompanies this memorandum, the exhibits to which are cited as "Ex. __."

[6] DefenCath's FDA approval may be judicially noticed because it can be accurately and readily determined from sources, namely FDA, whose accuracy cannot reasonably be questioned. *See In re Amarin Corp. PLC Sec. Litig.*, 2021 WL 1171669, at *11 (D.N.J. Mar. 29, 2021).

in the U.K and Japan.[7] Thus, ROVI manufactured products for many clients, not just CorMedix. *See* ¶ 164. In 2018, CorMedix hired a consultant, FE1, to do an FDA readiness assessment of ROVI. ¶ 81. According to FE2, the Senior Director of Quality Assurance from February 2020 until May 2023, FE1 prepared a 2019 audit report, in which FE1 allegedly recommended that ROVI not be used, and stated that ROVI would never be able to pass an FDA inspection. ¶¶ 82–83.[8] No further detail is alleged, including by the report's alleged author, FE1.

FDA Approval Process. Obtaining FDA approval to sell a new drug is a lengthy process. ¶ 56. If the clinical testing is successful and demonstrates safety and efficacy, the "sponsor" submits an NDA containing information about the testing as well as chemistry, manufacturing, and controls ("CMC"). ¶¶ 3, 57–58. After accepting an NDA for filing, FDA conducts a thorough review of the drug's safety and efficacy data, and it also evaluates the CMO by conducting an in-person "pre-approval inspection" of the CMO. ¶ 70. Pursuant to the Prescription Drug User Fee Act ("PDUFA"), FDA responds to the NDA within six months if the application is granted Priority Review. ¶ 15. FDA may respond with approval or a CRL. ¶¶ 72–73. A CRL does not preclude approval; in fact, a large percentage of NDAs do not obtain FDA approval during their first review cycle, after which the sponsor will typically seek to resubmit the NDA.[9]

CorMedix's Submission of the NDA. On October 16, 2019, CorMedix announced that it had met with FDA about the CMC information that CorMedix would submit in the NDA. ¶ 7.

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[7] *See* https://roviservices.com/injectable-certificates/.

[8] The CMO has since passed an FDA pre-approval inspection. *See* https://cormedix.com/cormedix-inc-reports-third-quarter-and-nine-month-2023-financial-results-and-provides-business-update/.

[9] For example, in 2020, the year CorMedix submitted the DefenCath NDA, only 53% of standard NDAs, and 81% of priority review NDAs, were approved during the first review cycle by FDA. All other filings received either a CRL or a Non Approvable Letter. *See* https://www.fda.gov/media/156077/download at 23.

FDA held this meeting at CorMedix's request; the CMO did not participate. *See* Ex. C at PDF p. 3–4. Following the meeting, CorMedix disclosed that "FDA was supportive of [DefenCath]'s proposed manufacturing program," but also reminded investors that FDA had not yet conducted a "thorough review of all the CMC information" or assessed the "commercial readiness of the various manufacturing facilities." ¶ 178. On November 14, 2019, CorMedix disclosed that "FDA did request some additional data" for the NDA that CorMedix was "working to complete[.]" ¶ 93.

In March 2020, CorMedix began the rolling submission process for the NDA. ¶ 203. On July 8, 2020, CorMedix completed its rolling submission of the DefenCath NDA. ¶ 98. On August 31, 2020, CorMedix announced that FDA had accepted the DefenCath NDA for filing and Priority Review. ¶ 206. FDA set a PDUFA date of February 28, 2021. ¶ 15.

Around the same time, COVID-19 was spreading globally. In July 2020, ROVI announced that it would procure a new production line and equipment to support the production of hundreds of millions of doses of Moderna's COVID-19 vaccine candidate. ¶ 163. Those operations were separate and apart from ROVI's DefenCath operations. *Id.*

CorMedix's Warnings that FDA Approval Was Uncertain. During the Class Period, CorMedix repeatedly warned investors that FDA approval of the DefenCath NDA was uncertain:

- "Regulatory approval of an NDA is not guaranteed. . . . The FDA can delay, limit or deny approval of a product candidate for many reasons[.]" Ex. D at 20; Ex. A at 22; Ex. E at 22; *see also* Ex. F at 17–19.

- "We do not have, and may never obtain, the regulatory approvals we need to market our product candidates outside of the European Union." Ex. D at 22; Ex. A at 17, 28; Ex. E at 17, 28; *see also* Ex. F at 17–19.

CorMedix also specifically warned about risks relating to manufacturing:

- "Before we could begin to commercially manufacture Neutrolin . . . we must obtain regulatory approval of the manufacturing facility and process. The manufacture of drugs . . . must comply with [current good manufacturing practices ("cGMP")] and applicable non-U.S. regulatory requirements. ***We would also have to pass a pre-approval inspection prior to FDA or non-U.S. regulatory agency approval. Failure***

to pass a pre-approval inspection may significantly delay regulatory approval." Ex. F at 27; Ex. D at 32; Ex. A at 37; Ex. E at 37.

- "***Our contract manufacturers may not be able to comply with the applicable FDA regulatory requirements***, which could result in delays to our product development programs, could result in adverse regulatory actions against them or us, and could prevent us from ultimately receiving product marketing approval." Ex. D at 33; Ex. A at 38; Ex. E at 38; Ex. F at 26–27.

March 2021 Complete Response Letter. On February 26, 2021, FDA issued a CRL to CorMedix ("First CRL"). FDA raised two principal issues in the First CRL. First, after a review of records requested by FDA from ROVI under Section 704(a)(4) of the Food, Drug, and Cosmetic Act, FDA noted "objectionable conditions," and stated that it would identify those conditions to the CMO within ten days. TAC Ex. 2 at 8. Second, FDA directed CorMedix to "conduct and provide results of an extraction study to demonstrate that the labeled volume of the drug product solution (5mL) can be consistently withdrawn from the vials . . . ." *Id.* at 9.

One business day after receipt of the First CRL, on March 1, 2021, CorMedix disclosed the First CRL to investors. ¶ 219. CorMedix informed investors that FDA had "noted concerns at the third party manufacturing facility" and that FDA "is requiring a manual extraction study." *Id.* CorMedix cautioned that "satisfactory resolution of these issues is required for approval of the DefenCath NDA[.]" *Id.* Then, on March 9, after FDA informed the CMO of the specific "deficiencies," CorMedix disclosed those "deficiencies" to investors. ¶ 223. One deficiency "result[ed] from the proposed future installation of new equipment" (for the Moderna vaccine); some deficiencies involved the "vial filling line" and the "target filling volume" for DefenCath vials, and another concerned an "airflow study." *Id.* These deficiencies were communicated by FDA to the CMO in a Post-Application Action Letter ("PAAL"). ¶ 125.

During the remainder of 2021, although CorMedix made progress towards resubmission of the NDA, it faced a number of setbacks, all of which were timely disclosed to investors. For

example, in May 2021, CorMedix informed investors that, based on its analyses, "additional process qualification will be needed with subsequent validation to address the deficiencies identified by FDA" pertaining to the vial filling operation. ¶ 129. Then, in September 2021, after ROVI announced contaminations found in certain batches of the Moderna vaccine, CorMedix disclosed that it had been informed by the CMO that there were "issues unrelated to DefenCath manufacturing activities" that would delay the "timeline for CorMedix and the CMO to address deficiencies at the facility that are required for resubmission of the DefenCath NDA[.]" ¶¶ 261.

On February 4, 2022, the manufacturer of DefenCath's API heparin received an FDA Form 483 due to "manufacturing deficiencies." ¶ 149.[10] Plaintiff does not quote from the Form 483 or otherwise allege any facts as to the nature of the findings therein or whether they had anything to do with the API for DefenCath. Nor does Plaintiff allege that this Form 483 was ever shared with CorMedix (or the Individual Defendants) or when.

DefenCath NDA Resubmission. On February 28, 2022, CorMedix announced that it resubmitted the NDA. ¶ 144. In the accompanying press release, CorMedix stated that "[w]e believe that we and the [CMO] have adequately addressed the concerns the Agency identified in the CRL and PAAL." *Id.*; Ex. G at 2. On March 28, 2022, CorMedix announced that FDA had begun review of the re-submitted NDA and scheduled an onsite inspection of the CMO. ¶ 267. The FDA set a PDUFA date for the re-submitted NDA in August 2022. ¶ 147; Ex. H at 1–2.

August 2022 Complete Response Letter and Warning Letter to API Supplier. On June 30, 2022 (*see* SAC ¶ 245), the API supplier received a "Warning Letter" from FDA as a result of

[10] Following an inspection, FDA investigators may list "inspectional observations" on an FDA Form 483. ¶ 172. "A Form 483 contains advisory language that makes clear it lists only inspectional observations and do[es] not represent a final agency determination regarding your compliance." *In re Genzyme Corp. Sec. Litig.*, 754 F.3d 31, 35 (1st Cir. 2014).

manufacturing deficiencies for an API unrelated to DefenCath. ¶ 281. On August 4, 2022, FDA issued a second CRL (the "Second CRL"). TAC Ex. 2 at 2; ¶ 281.

On August 8, 2022, CorMedix disclosed that the Second CRL was received "from the FDA stating that the DefenCath NDA cannot be approved until deficiencies *recently conveyed* to the [CMO] and [API supplier] during inspections are resolved[.]" ¶ 281 (emphasis added). CorMedix disclosed that, following FDA's issuance of the Warning Letter to the API supplier, the Company sought "guidance" from the FDA about the deficiencies at the API supplier and any potential impact on the DefenCath NDA approvability, and CorMedix was informed "by way of the CRL" that the deficiencies must be resolved before NDA approval may be granted. Ex. I at PDF p.3.

ARGUMENT

To plead a violation of Section 10(b) of the Exchange Act and Rule 10b-5, Plaintiff must allege "(1) a material misrepresentation or omission, (2) scienter, (3) a connection between the misrepresentation or omission and the purchase or sale of a security, (4) reliance upon the misrepresentation or omission, (5) economic loss, and (6) loss causation." *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 167 (3d Cir. 2014).

Plaintiff's burden is heightened by the pleading standards of Rule 9(b) and the PSLRA, which the Third Circuit "rigorously" applies. *GSC P'ners CDO Fund v. Wash.*, 368 F.3d 228, 236 (3d Cir. 2004). Under Rule 9(b), "'in all averments of fraud . . ., the circumstances constituting fraud . . . shall be stated with particularity.'" *Id.* (quoting Fed. R. Civ. P. 9(b)). The PSLRA "imposes another layer of factual particularity to allegations of securities fraud." *Id.*

I. The TAC Fails To Adequately Allege Scienter

To adequately plead scienter under the PSLRA, a plaintiff must "'state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind' . . . which [the Third Circuit has] described as one 'embracing [an] intent to deceive, manipulate, or

defraud,' either knowingly or recklessly." *In re Hertz Glob. Holdings Inc.*, 905 F.3d 106, 114 (3d Cir. 2018). In the securities context, "[t]o plead a 'knowing or reckless state of mind,'" a plaintiff "must plead 'an extreme departure from the standards of ordinary care.'" *Smith v. Antares Pharma, Inc.*, 2021 WL 754091, at *5 (D.N.J. Feb. 26, 2021).

No Scienter Pled Against Individual Defendants. Scienter must be pled on a defendant-by-defendant basis. *See Winer Fam. Tr. v. Queen*, 503 F.3d 319, 337 (3d Cir. 2007). But Plaintiff does not event attempt to do that here, making no individualized allegations of scienter against the Individual Defendants. None of the Individual Defendants were alleged to have sold stock during the Class Period or to have any other motive to commit securities fraud. To the contrary, during the Class Period, all but one of the Individual Defendants ***bought*** CorMedix stock; none sold stock. Ex. J. This is a fact that raises a compelling inference against scienter. *See In re Adolor Corp. Sec. Litig.*, 616 F. Supp. 2d 551, 572–73 (E.D. Pa. 2009).

As to what is pled against the Individual Defendants, Mr. Cook was employed for only about three months in the Class Period. ¶ 49. Mr. Cook departed CorMedix several months *before* the NDA was submitted. Further, Mr. Cook was the former CFO; no allegations are pled supporting Mr. Cook would have known about alleged CMC deficiencies. To the contrary, Mr. Cook is only mentioned by name three times in the TAC—twice where he is listed as a defendant (¶¶ 49, 55), and once where he is alleged to have signed an SEC filing (¶ 178). The same holds true of Mr. Cook's successor, Dr. David. Dr. David is named in the TAC only as a "Defendant" (¶ 49), "Individual Defendant" (¶ 55), and where he is alleged to have spoken on a conference call or signed an SEC filing (¶¶ 140, 148, 204, 212, 231, 254). No facts are pled supporting a plausible inference that as the CFO, he was aware of undisclosed risks to FDA approval of the NDA. *See*

In re Par Pharm. Sec. Litig., 2008 WL 2559362, at *10 (D.N.J. June 24, 2008) ("Plaintiffs do not even attempt to allege specific facts to show scienter on the part of the new CFO.").

Mr. Todisco became the CEO of CorMedix on May 10, 2022. ¶ 54. By then, CorMedix had already received and disclosed the First CRL (¶ 21) and made all but one of the alleged corrective disclosures that Plaintiff claims revealed the Company's fraud to the market (¶ 281). Nothing is pled to support that the few statements Mr. Todisco made between his hire on May 10, 2022 and the end of the Class Period on August 8, 2022—generally concerning the fact that FDA was conducting a pre-approval inspection of the CMO (¶¶ 274, 279)—were fraudulent.[11] Likewise, as set forth below, no individualized scienter allegations are made against Mr. Armstrong, Ms. Mounts, or Mr. Baluch.[12]

No Access to Contrary Facts. The TAC lacks allegations that the Defendants knew facts about DefenCath's approval prospects that ran counter to their public statements. At most, the TAC alleges that a 2018 FDA readiness audit, resulting in a 2019 report, purportedly found the CMO would never pass FDA inspection and recommended a different CMO be used. ¶¶ 81–83.

At the outset, this allegation lacks particularization and sufficient indicia of reliability to be credited under the PSLRA. In the Third Circuit, courts "consider the detail provided by the confidential sources, the sources' basis of knowledge, the reliability of the sources, the corroborative nature of other facts alleged, including from other sources, the coherence, and

[11] *See Acito v. IMCERA Grp., Inc.*, 47 F.3d 47, 53 (3d Cir. 1995) (refusing to infer scienter based on failed FDA inspection because plaintiff failed to plead facts sufficient to support "it was a 'foregone conclusion' that the Kansas City plant would fail the inspection and adverse consequences would ensue").

[12] Plaintiff's failure to plead scienter for the Individual Defendants, or for any other CorMedix employee, forecloses any inference of corporate scienter against CorMedix. *See Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 246 n.14 (3d Cir. 2013) (noting "the most straightforward way" to plead scienter for "corporate defendant will be to plead it for an individual defendant.").

plausibility of the allegations, and similar indicia." *Institutional Invs. Group v. Avaya, Inc.*, 564 F.3d 242, 261 (3d Cir. 2009) (internal citation omitted). "If the anonymous source allegations are found wanting with respect to these criteria, then we must discount them steeply." *Id.* at 263.

Here, Plaintiff's allegations about the audit report, sourced from FE2, merit a steep discount. ***First***, Plaintiff fails to allege that FE2 had first-hand knowledge of the audit report. *See Chan v. New Oriental Educ. & Tech. Grp. Inc.*, 2019 WL 2865452, at *11 (D.N.J. July 3, 2019) (finding no scienter pled where "no details are given about how or when a confidential witness learned of the information he or she provides, or if the information comes from first-hand knowledge"). FE2 is not alleged to have even *read* the audit report; FE2 did not start working at CorMedix until February 2020, years after the audit and well after the report. ¶ 82. Furthermore, FE2 is not alleged to have ever worked with or spoken with FE1, the principal consultant of the audit, and FE1, who despite being a purported cooperating witness, does not corroborate FE2's characterization of the report or say ***anything*** about what his audit supposedly found. *See Avaya*, 564 F.3d 242 at 261 (courts evaluate "corroborative nature" of confidential witness allegations). ***Second***, FE2's allegations about the audit report cannot be credited because they are contradicted by Plaintiff's own allegations. To wit, FE2 claims that ROVI was chosen by CorMedix "*despite*" the audit report, ¶ 84 (emphasis added), but that cannot possibly be correct because, according to Plaintiff, CorMedix "selected" ROVI as "its CMO" *in 2017*, ¶ 79, while the audit was not performed until 2018. *See Industriens Pensionsforsikring A/S v. Becton*, 2021 WL 4191467, at *18, n.32 (D.N.J. Sept. 15, 2021) ("contradictions call into question the reliability of Plaintiff's [confidential] witnesses"). ***Third***, FE2's allegations about the audit report are not sufficiently particularized to be credited. FE2 does not offer any details about how the audit was performed, its scope, what deficiencies it supposedly found, and how they related, if at all, to the deficiencies

later identified in the CRLs. *See In re Intelligroup Sec. Litig.*, 527 F. Supp. 2d 262, 360 (D.N.J. 2007) (collecting cases disregarding "vague and conclusory" or "generalized" confidential witness allegations); *Nat'l Junior Baseball League v. Pharmanet*, 720 F. Supp. 2d 517, 546 (D.N.J. 2010) (refusing to credit CW11's allegation of performance issues when, among other reasons, "CW11 did not state what specifically were the performance issues").

In any event, the claim that "Defendant Baluch was closely involved in the production and distribution" of the report and that FE2 "*believes* that Defendant Mounts received a copy of it" falls far short of giving rise to a strong inference of scienter under the PSLRA. ¶ 86. By the time the Defendants spoke, the 2019 report and the 2018 audit on which it was based were ***stale***. *See Emps. Ret. Sys. of City of Providence v. Embraer S.A.*, 2018 WL 1725574, at *11 (S.D.N.Y. Mar. 30, 2018) (allegations of bribery years prior to the class period were "temporally and logically insufficient" to infer that the company's internal controls during the class period were not effective). And because FE2 was not employed at CorMedix in 2018 and 2019, she has no personal knowledge of what the Company did in response to the audit. ¶ 82; *see Rahman*, 736 F.3d at 245 (discounting "CW2" allegations about company's improper re-labelling of imported furniture from China because CW2 "did not begin working for [the company] until June 2011, so CW2 cannot have personal knowledge regarding the pre-investigation violations" that allegedly formed the basis of the fraud). Nor does she offer any facts suggesting that when she joined CorMedix in 2020, the CMO was not in a position to pass an FDA inspection.

Providing no detail about what the audit found or why, all that is pled is FE1's alleged *opinion* (as described by FE2, no less) about the CMO's readiness for an FDA inspection years prior to submission of the NDA, which cannot give rise to a strong inference of scienter. *Winer Fam. Tr.*, 503 F.3d at 332–33 (affirming employee's "opinion could not give rise to a strong

inference that [Defendant] acted with scienter"). There is no allegation that anyone at CorMedix adopted FE1's alleged opinion. *See id.* And the allegation that CorMedix selected the "wrong" CMO, a dubious proposition given the NDA was ultimately approved following a successful FDA inspection of the CMO, alleges at worst, mismanagement, *not* fraud. *Acito*, 47 F.3d at 53 ("It is well settled that section 10(b) was not designed to regulate corporate mismanagement.").

Beyond that, the TAC relies on generalities about "concerns raised by the FDA regarding meeting CMC standards" (¶ 293) and nonspecific allegations, such as "[t]he Individual Defendants possessed the requisite scienter as they had the power and authority to control the contents of CorMedix's SEC filings" (¶ 294). But that is as far as the TAC goes. Despite reviewing various FDA touchpoints, at no point does the TAC identify *what* concerns were raised by FDA, *when*, or *how* Defendants became aware of them. *See Monk v. Johnson & Johnson*, 2011 WL 6339824, at *7 (D.N.J. Dec. 19, 2011) (PSLRA requires "the who, what, when, where and how" of the fraud). To the extent Plaintiff seeks to plead scienter through the Form 483 issued by FDA to the CMO or API supplier, courts have rejected that theory of scienter given the provisional and observational nature of a Form 483. *Genzyme*, 754 F.3d at 35. Nor does Plaintiff plead how and when Defendants became aware of the Form 483s.

No "Core Operations" Doctrine. Plaintiff rests principally on the "core operations" doctrine, which holds that where misrepresentations touch on "core matters of central importance" to the corporate defendant, a "core operations inference" may support scienter. *See In re Celgene Corp. Sec. Litig.*, 2019 WL 6909463, at *20 (D.N.J. Dec. 19, 2019) (internal citation omitted). However, such an inference is unavailable "at least absent some additional allegations of the specific information conveyed to management and related to the fraud." *Avaya*, 564 F.3d at 270 (internal citation omitted). Where such allegations are absent, as here, courts have refused to infer

scienter on that basis. *See Hoey v. Insmed Inc.*, 2018 WL 902266, at *23 (D.N.J. Feb. 15, 2018) (no core operations inference where plaintiff failed to allege other individualized allegations that defendants had knowledge of the facts at issue); *In re Heartland Payment Sys., Inc. Sec. Litig.*, 2009 U.S. Dist. LEXIS 114866, at *21 (D.N.J. Dec. 7, 2009) (rejecting core operations inference because "it is not automatically assumed that a corporate officer is familiar with certain facts just because these facts are important to the company's business; there must be other, individualized allegations that further suggest that the officer had knowledge of the fact in question.").

Equally unavailing are Plaintiff's variations on the "core operations" theory, namely that scienter can be inferred from Defendants' corporate positions (¶¶ 294, 296), industry experience (¶¶ 48–52, 54), or by virtue of purportedly holding themselves out as knowledgeable on the subject of the NDA or FDA approval process (¶¶ 93, 184). Allegations that a defendant, "because of his position . . . 'must have known' a statement was false or misleading are precisely the types of inferences which [courts], on numerous occasions, have determined to be inadequate." *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 539 (3d Cir. 1999) (internal citation omitted). Neither does general industry experience support a compelling inference of scienter. *In re Synergy Pharma., Inc. Sec. Litig.*, 2021 WL 4480625, at *14 (E.D.N.Y. Sept. 30, 2021). Nor did Plaintiff plead that any of the Defendants held themselves out as having first-hand knowledge of specific data that contradicted their public statements. *See Amarin*, 2021 WL 1171669 at *18 (rejecting inference of scienter based on allegations defendants' statements implied first-hand knowledge of matter at issue).

Remaining Scienter Allegations Are Insufficient. "The Third Circuit has generally found resignations of key officers to be insufficient to show that they acted with the requisite scienter to commit the alleged fraud." *In re Par Pharm. Sec. Litig.*, 2008 WL 2559362, at *12

(finding scienter insufficiently pled on this basis) (internal quote omitted). For the resignations of Mr. Baluch and Mr. Armstrong (¶¶ 48, 52, 137) to constitute a "piece to the scienter puzzle," Plaintiff must plead that "the resignation both takes place within a couple of months of the announcement of errors committed and is accompanied by an extraordinary corporate punishment measure, e.g., denial of severance payment." *Insmed Inc.*, 2018 WL 902266, at *23. Otherwise, an officer's departure leads to "the reasonable assumption that the resignation occurred as a result of the release of bad news." *Hertz*, 905 F.3d at 118–19. Both departing officers retired, Mr. Baluch remained as an advisor, and Plaintiff does not (and cannot) allege that either were denied severance benefits. ¶ 137; Ex. K at 1–2. That the resignations occurred on October 2, 2021 (¶ 137), *seven months* after announcement of the First CRL, further undermines any inference of scienter. *See Intelligroup*, 527 F. Supp. 2d at 347.

"An allegation that a defendant signed a SOX certification . . . does not add to the scienter puzzle in the absence of any allegation that the defendant knew he was signing a false SEC filing or recklessly disregarded inaccuracies." *Hertz*, 905 F.3d at 118; ¶¶ 204, 212, 231, 254 (Baluch and David signed certifications). There are no allegations here that CorMedix filed false financial statements or had inadequate financial controls.

The Non-Culpable Inference Is Stronger. In assessing scienter, "courts must analyze the complaint holistically to determine whether its allegations, 'taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard.'" *Hertz*, 905 F.3d at 114. Indeed, a plaintiff clears the high hurdle imposed by the PSLRA's pleading requirements "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 310. Taking the TAC as a whole, the much more compelling inference is that

Defendants, while disclosing the risks, sincerely believed that DefenCath would be approved by FDA, provided regular updates to investors on the status of the NDA, but experienced some significant setbacks at third-party suppliers and manufacturers during the pandemic.

Three considerations render the nonculpable inference (a disappointing outcome) substantially stronger than the culpable inference (fraud). First, much like in *In re Genzyme Corp. Sec. Litig.*, 754 F.3d 31, 44 (1st Cir. 2014), "defendants' statements were positive yet generally qualified, were accompanied by relevant exchanges with the FDA, and generally tracked the PDUFA dates set by the FDA." Indeed, Defendants never guaranteed approval of the NDA much less by a date certain; instead, they warned investors of potential risks (*see supra* at pp. 7–8) and repeatedly sounded a cautionary note, including, for instance, telling investors on the very first day of the Class Period that FDA had yet to conduct a "thorough review of all the CMC information" or assessed the "commercial readiness of the various manufacturing facilities" (*see supra* at p. 7). Second, as noted, CRLs are not uncommon, even for drugs that ultimately succeed in attaining FDA approval. *See supra* at p. 6. And the root causes of the First CRL and Second CRL were not deficiencies in the NDA, manipulated data, or flawed clinical trials, but manufacturing and supply issues at third parties that did not relate to the NDA data (and many not to DefenCath at all). *See supra* at pp. 8–10. Finally, the attempt to plead fraud by hindsight is particularly misplaced in this case because DefenCath *was approved* by the FDA following the Class Period. *See supra* at p. 5.

II. The TAC Fails To Adequately Allege Any False Or Misleading Statements

Under the PSLRA, Plaintiff must "'specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading[.]'" *Bauer v. Eagle Pharms., Inc.*, 2017 WL 2213247, at *5 (D.N.J. May 19, 2017). The "statement or omission must have been misleading at the time it was made; liability cannot be imposed on the basis of subsequent events." *Id.* Plaintiff challenges over 50 statements made by Defendants between October 16, 2019 and

June 15, 2022. Much of the TAC appears premised on challenging guarantees of FDA approval Defendants ***never*** made, such as that "investors were misled into believing that . . . there was no risk of CorMedix receiving anything other than FDA approval." ¶ 139. The statements Defendants actually made correspond generally to the four categories addressed below. Plaintiff fails to allege particularized facts supporting that any statements were false or misleading when made.

A. True Statements Before the First CRL

Plaintiff claims that a number of truthful statements prior to the First CRL (March 1, 2021) were misleading. These statements are set forth in Appendix A.[13] They include statements about the submission of the NDA, statements about various interactions with the FDA before and after submission of the NDA, and certain risk warnings to investors, such as the CMO "may not be able to comply with the applicable FDA regulatory requirements, which . . . could prevent us from ultimately receiving product marketing approval" (¶¶ 190–91).[14] Plaintiff claims that these statements were misleading principally because "FDA had already raised concerns to CorMedix regarding the CMC information presented" and the 2018 audit of ROVI had identified "deficiencies," both of which supposedly meant the "DefenCath NDA submission lacked sufficient evidence and could not obtain FDA approval in the second half of 2020." ¶ 180.

As an initial matter, virtually none of the statements set forth in Appendix A amounts to "affirmative characterizations regarding" the likelihood of FDA "approval" of the DefenCath NDA, or the timing of a decision from FDA. *Amarin*, 2022 WL 2128560, at *3. In other words,

[13] ¶¶ 223-24, 227, 229-30, 233-34, 239-40, 249, 252-53, 257-59, 270, 272, 274, 276-77, 279.

[14] Plaintiff fails to allege that these "risk factors" were false because he fails to allege that the "risk[s] actually warned" of—"delays to [CorMedix's] product development programs, . . . adverse regulatory actions against [the CMO] or [CorMedix]," or "prevent[ing] [CorMedix] from ultimately receiving product marketing approval," ¶¶ 190–91; Ex. D at 33—had "materialized . . . at the time the risk disclosures were made," i.e., March 16, 2020. *Williams v. Globus Med., Inc.*, 869 F.3d 235, 242–43 (3d Cir. 2017).

as the court held in *In re Amarin Corporation PLC Securities Litigation*, the challenged statements do not put "in play" the allegedly omitted information and are therefore not misleading. *Amarin*, 2021 WL 1171669 at *15.

In any event, Plaintiff fails to plead any "concerns" raised by FDA prior to the First CRL. Plaintiff alleges that FDA's request for "additional data" from CorMedix in late 2019 "reflected the existence of deficiencies" at the CMO, including those later identified in the First CRL. ¶ 205. But that allegation rests on nothing more than Plaintiff's speculation. In fact, the well-pleaded facts alleged in the TAC reveal that the First CRL was a result of FDA's review of records *requested from ROVI*, not any "data" requested *from CorMedix* before the NDA was submitted. *See* ¶ 105 (First CRL identified "manufacturing issues that were readily apparent *from records provided by ROVI*") (emphasis added). Regardless, a mere request for data or records is not the same as "raising concerns" about the NDA.[15] In a similar case, this Court held that "the fact that the [defendant pharmaceutical company] was admittedly engaged in an ongoing dialogue with the FDA" did not give rise "to the inference that the FDA . . . *expressed concerns* that required follow-up prior to the release of the CRL." *Bauer*, 2017 WL 2213147, at *9 (emphasis added). Indeed, Plaintiff now appends FDA's "Meeting Preliminary Comments" sent to CorMedix on November 7, 2019 to its TAC, and those comments reveal no "concerns" about the CMO. TAC Ex. 1.

Unable to allege that FDA had communicated "concerns" to CorMedix prior to the First CRL, Plaintiff relies on its allegation that, according to FE2, a 2018 outside audit report concluded

[15] It would be insufficient that FDA communicated *any* concerns to Defendants. *In re Amarin Corp. PLC Sec. Litig.*, 689 F. App'x. 124, 132 (3d Cir. 2017) (observing that "continuous dialogue between the FDA and the proponent of a new drug is the essence of the product license application process."). Rather, Plaintiff must allege "that the FDA's concerns [] were so serious as to place . . . FDA approval of [DefenCath] in jeopardy." *Amarin*, 2016 WL 1644623, at *18.

the CMO "would never be able to pass an FDA inspection." ¶ 83.[16] As set forth in Section I, *supra*, this allegation should not be credited. Regardless, it does not contradict any of Defendants' pre-CRL statements, which do not speak to the CMO's ability to pass FDA inspection.[17]

B. True Statements After the First CRL

Plaintiff likewise challenges a number of truthful statements Defendants made after CorMedix's disclosure of the First CRL on March 1, 2021. These statements are set forth in Appendix B[18] and include accurate descriptions of the First CRL and PAAL (¶ 223; *see also* ¶¶ 229, 230, 252), statements that CorMedix was "working with" the CMO and accurate descriptions of the status of the remediation efforts (¶ 229), and warnings after resubmission of the NDA about the upcoming FDA inspection of the CMO (¶ 274).[19]

As with the pre-CRL statements, Plaintiff claims these post-CRL statements were false because Defendants failed to disclose "material adverse facts" that supposedly indicated the

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[16] Plaintiff does not allege that any statements after the First CRL were rendered false on account of the audit report.

[17] In July 2020, CorMedix attributed the delay in submitting the NDA to "limitations imposed by the COVID-19 pandemic[.]" ¶ 199. Plaintiff alleges this statement was false because "the delayed submission [was] *more likely* a result of" deficiencies at the CMO. ¶ 200 (emphasis added). Not only is this allegation devoid of factual support, courts have rejected as inadequately pled similar allegations that statements were "likely" false. *See Amarin*, 2016 WL 1644623, at *18 (allegations that FDA "likely" expressed "concerns" were "insufficient" under Rule 9(b) and the PSLRA).

[18] ¶¶ 223-24, 227, 229-30, 233-34, 239-40, 249, 252-53, 257-59, 270, 272, 274, 276-77, 279.

[19] Plaintiff fails to allege that the "3 commercial scale drug product batches" of DefenCath that ROVI manufactured did not "meet specifications," and therefore fails to allege that Mr. Armstrong's March 9, 2021 statement about drug batches previously manufactured at the CMO was false when made. ¶ 224. Nor does Plaintiff allege that CorMedix was not "following the guidelines on overfill." ¶ 227. The language that Plaintiff highlights from CorMedix's "Corporate Presentation"—stating that CorMedix had "successfully concluded technical transfer and validation of the drug product manufacturing process," ¶ 240—in context, has nothing to do with the NDA. Ex. L at 18. And that same presentation disclosed receipt of the First CRL (Ex. L at 3, 10), making clear that the "manufacturing process" was under FDA scrutiny. Finally, statements to investors that CorMedix was "anticipat[ing] potential supply chain challenges" were also unrelated to the NDA and are not alleged to have been false. *See* ¶¶ 272, 276.

CMO's remediation efforts would be "delayed" and that FDA approval of the NDA was at "high risk." *E.g.*, ¶¶ 255, 273. However, for the most part, the challenged statements set forth in Appendix B do not "put into play" the likelihood of success of the NDA. *Amarin*, 2022 WL 2128560, at *3. But even if they did, Plaintiff fails to identify any undisclosed "material adverse facts" that called into question approval of the NDA.

Within the time frame of these challenged statements—March 9, 2021 to June 15, 2022—the TAC does not allege that FDA provided any undisclosed negative feedback. Plaintiff identifies only one meeting between CorMedix and FDA during that time (on April 14, 2021), but does not allege that Defendants inaccurately disclosed what happened at the meeting. ¶ 236.

Instead, Plaintiff relies on his allegation that, in mid-2021, ROVI allegedly manufactured "contaminated vials" of the Moderna vaccine due to "protocols relating to changeover of manufacturing lines." ¶¶ 166–67, 260. But there are no allegations that, at the time the challenged statements were made—or, for that matter, at any time after the First CRL—FDA had given "any indication" that the vaccine contamination issues would "hinder approval" of the DefenCath NDA. *Genzyme*, 754 F.3d at 43 (no obligation to disclose bioreactor failures at one plant where failures "bore no relation to FDA approval of the Lumizyme [application] for production" at another plant and FDA had not given "any indication that the bioreactor run failures would hinder approval" of the application). To the extent Plaintiff is claiming that CorMedix should have disclosed that ROVI's vaccine contamination issues would "delay" *resubmission* of the NDA, *e.g.*, ¶ 260, CorMedix did just that when, on September 7, 2021, it disclosed that "delays at its third party [CMO]" from "issues unrelated to DefenCath manufacturing activities" would delay the "timeline for CorMedix and the CMO to address deficiencies at the facility that are required for resubmission of the" NDA. ¶ 261; *see also* ¶ 164.

Plaintiff also claims that Defendants' post-CRL statements were misleading because Defendants failed to disclose that the third-party heparin supplier received an FDA Form 483 on February 4, 2022. *E.g.*, ¶ 280. But Plaintiff does not adequately allege that the supplier's receipt of a Form 483—much less one that is not alleged to have implicated the supplier's production of DefenCath's API —contradicted any of the challenged statements. *In re Genzyme Corp. Securities Litigation* is instructive. 754 F.3d at 42. In that case (unlike here) the CEO of the defendant company itself received the Form 483. *Id.* at 41. The First Circuit determined that the defendants' statements following receipt of the Form 483 "touting positive projections" for the drug product were not misleading, because the Form 483 "did not state" that the drug application in question "had been compromised." *Id.* Therefore, defendants had no obligation to disclose the Form 483 until subsequent FDA communications "crystalized the relevance of the . . . Form 483," which occurred after Genzyme received a CRL. *Id.* at 41–42. The same thing happened here: there are no allegations that the Form 483 sent to the supplier indicated that the NDA had been "compromised," and as soon as FDA communicated to CorMedix that deficiencies at the supplier would hinder the NDA (through a CRL), Defendants informed investors. ¶ 281; Ex. I at PDF p.3.[20]

[20] Plaintiff's other alleged grounds for falsity with respect to post-CRL statements are conclusory and contradictory. For example, Plaintiff claims that Defendants failed to disclose that "it would be necessary for the CMO to collect additional data, including but not limited to, an airflow visualization study." *E.g.*, ¶ 241. But CorMedix had *already disclosed* on March 9, 2021, *before* the challenged post-CRL statements, that an airflow visualization study would be required. ¶ 119. Plaintiff also claims that statements on June 15, 2022 about "moving in the right direction" were misleading because Defendants failed to disclose that "FDA was still criticizing CorMedix's manufacturing process." ¶ 280. But there are no allegations that, as of June 15, 2022, FDA was criticizing CorMedix's "manufacturing process"—only that FDA had issued a Form 483 to its API supplier. *Eagle Pharms.*, 2017 WL 2213147, at *7 ("speculation and conjecture will not support a claim under the PSLRA[]"). Other alleged omissions, for example, that "the CMO would need to conduct additional process qualification," ¶ 228, are unsupported by contemporaneous factual allegations and rely instead on pleading by hindsight.

C. Forward-Looking Statements Protected by Safe Harbor

Many of the challenged statements are "forward-looking" statements subject to a statutory "Safe Harbor" under the PSLRA, including statements about the timeline for a decision on the NDA, that CorMedix remains "on schedule" for its NDA submission, and the Company's prospects for remediating the issues raised in the First CRL and resubmitting the NDA. *See* Appendix C.[21] The PSLRA "immunize[s] any forward-looking statement provided that *either* it is 'accompanied by meaningful cautionary statements' or 'the plaintiff fails to prove that the forward-looking statement . . . was made with actual knowledge . . . that the statement was false or misleading.'" *OFI Asset Mgmt. v. Cooper Tire & Rubber*, 834 F.3d 481, 502–503 (3d Cir. 2016) (emphasis in original) (quoting 15 U.S.C. § 78u–5(c)(1)).

The challenged statements set forth in Appendix C were identified as forward-looking statements. *E.g.*, Ex. M at 1 ("This press release contains forward-looking statements within the meaning of the [PSLRA] that are subject to risks and uncertainties."). Courts in this Circuit have held that similar statements about a drug's potential FDA approval are forward-looking. For example, the court in *In re Egalet Corp. Securities Litigation* observed that "courts in this circuit have repeatedly found that statements regarding the likelihood and timing of FDA approval for a drug and the reasons for management's beliefs that such approval will occur fall under the statutory definition of forward-looking," and concluded that statements such as "'we are on track to meet our goals for the year'" were forward-looking. 340 F. Supp. 3d 479, at 502 (E.D. Pa. Aug. 2, 2018). Likewise, in *Bauer v. Eagle Pharmaceuticals*, the court held that "statements relating to anticipated FDA approval" are forward-looking, including statements such as "'we have every expectation that based on our file and the dialogue that's been ongoing [with FDA] that we'll get

[21] ¶¶ 179, 187, 194, 196, 223, 243, 256, 257, 258.

an approval"' and "'we continue to expect an FDA decision in March 2016.'" 2017 WL 2213147, at *8–9. Courts have also held that statements following receipt of a CRL and Warning Letter "project[ing] the company's belief that the problems related to the [FDA application] were being addressed" and expressing "the expectation that . . . approval would come about at some point later in 2009" were forward-looking. *Genzyme*, 754 F.3d at 45.

The challenged forward-looking statements were also accompanied by meaningful cautionary language. Each was prefaced by its own cautionary language warning, for example, that "actual results may differ materially from projections or estimates due to a variety of important factors, including . . . risks related to the timing of and our ability to obtain FDA approval of the [NDA] for Neutrolin[.]"[22] The statements also incorporated by reference the cautionary language set forth in CorMedix's periodic SEC filings, which specifically warned investors that the NDA and resubmitted NDA may never be approved.[23] CorMedix further warned that approval may be delayed or never occur at all *due to manufacturing issues*. *E.g.*, Ex. A at 37 ("[f]ailure to pass a pre-approval inspection may significantly delay regulatory approvals of our products"); *id.* at 38 ("Our [CMO] may not be able to comply with the applicable FDA regulatory requirements, which could result in delays"). Thus, CorMedix, "in no uncertain terms, warned investors" of "the risks that came to fruition and [that] form the basis of Plaintiff['s] complaint." *Eagle Pharms.*, 2017 WL 2213147, at *11; *see also id.* at *10 (finding that similar risk disclosures in the context of anticipated FDA approval of an NDA constituted "meaningful cautionary language").[24]

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[22] Ex. N at 1; *see also* Ex. M at 1; Ex. O at 1; Ex. P at PDF p.4; Ex. Q at PDF p.3; Ex. R at PDF p.3; Ex. S at PDF p.3; Ex. T at PDF p.3.

[23] Ex. F at 17–19; Ex. D at 20, 22; Ex. A at 17, 22, 28; Ex. E at 17, 22, 28.

[24] Because the challenged statements were forward-looking and accompanied by sufficient cautions, the Court need not consider whether the makers of the statements had "actual knowledge"

D. Opinion Statements and Non-Actionable Statements of Corporate Optimism

Lastly, a significant number of the challenged statements are non-actionable statements of corporate optimism and/or opinion statements. *See* Appendix D. "Vague and non-specific expressions of corporate optimism" or "puffery" are immaterial as a matter of law. *In re Aetna, Inc. Sec. Litig.*, 617 F.3d 272, 283–84 (3d Cir. 2010). Opinion statements are misleading only if the complaint alleges the opinion (i) was not sincerely held by the speaker when made; (ii) contains a false "embedded statement of fact"; or (iii) omits to disclose facts that would "conflict with what a reasonable investor would take from the statement itself." *Omnicare, Inc. v. Laborers Dist. Council*, 575 U.S. 175, 188–89 (2015); *see also City of Warren Police and Fire Ret. Sys. v. Prudential Fin., Inc.*, 70 F.4th 668, 685 (3d Cir. 2023) (adopting *Omnicare*'s framework for evaluating "opinion falsity" under Section 10(b) claims). Satisfying this standard is "no small task for an investor," and opinion statements are not false merely because the speaker omits facts that "cut[] the other way." *Omnicare*, 575 U.S. at 190, 194.

Statements About Having the "Right Team". Plaintiff challenges a number of statements made by Messrs. Armstrong and Baluch about the CorMedix "team," such as having "a very experienced and competent team" (¶ 185), having "the team" (¶¶ 202, 210), and having "the right team and appropriate resources" (¶ 232). *See also* ¶¶ 225, 250–51, 257. These are exactly the types of vague, unverifiable statements that courts have found to be non-actionable statements of optimism. For example, in *Southeastern Penn. Transp. Auth. v. Orrstown Fin. Services, Inc.*, the court determined that defendant's advertising of its "deep and experienced

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of the falsity of the statements. *Cooper Tire*, 834 F.3d at 502–503. But even if actual knowledge were relevant, as explained in Section I, *supra*, Plaintiff fails to allege that any of the makers of the forward-looking statements acted with scienter, and "actual knowledge" is a "more demanding standard of scienter than applies to statements of current fact." *Avaya*, 564 F.3d at 259, n.29.

management team with strong community ties, operational ability and proven track record of acquisition integration" was non-actionable puffery. 2015 WL 3833849, at *30 (M.D. Pa. June 22, 2015).[25]

Opinions that CorMedix Had Adequately Addressed FDA Concerns. Plaintiff also challenges various statements by Ms. Mounts, Mr. Baluch, and Mr. Todisco expressing their opinion that CorMedix had adequately addressed the deficiencies identified by FDA in the First CRL, such as, for example: "We believe that we and the manufacturer have adequately addressed the concerns [FDA] identified in the CRL and PAAL." ¶ 266; *see also* ¶¶ 267-68, 279.

Plaintiff fails to allege that the stated opinions were not sincerely held (*see* Sec. I, *supra*), or that they omitted facts that would conflict with what a reasonable investor would take from the statements themselves. Plaintiff does not allege that FDA's "concerns" identified in the First CRL and PAAL were *not* addressed at the time the challenged statements were made. *Omnicare*, 575 U.S. at 188. In fact, there are no allegations that the Second CRL identified the same concerns FDA had identified in the First CRL and PAAL. Moreover, a reasonable investor would have read these opinion statements in context with Defendants' risk disclosures warning, among things, that FDA approval was "not guaranteed." *See Amarin*, 689 F. App'x at 132 (falsity not alleged because "reasonable investor" would not have read statements as "presenting a clear path to approval . . . given Amarin's contemporaneous [risk] disclosures").

Sarbanes-Oxley Certifications. Finally, Plaintiff challenges Sarbanes-Oxley certifications signed by Mr. Baluch and Dr. David in connection with various SEC filings. *E.g.*, ¶ 192. These certifications stated that "to my knowledge . . . the information contained in the

[25] Mr. Todisco's opinion statement on June 15, 2022—"so from everything that we can see, I'm optimistic that everything is moving in the right direction," ¶ 279—was non-actionable puffery.

Report fairly presents, in all material respects, the financial condition and results of operations of the Company." *E.g.*, Ex. U. These are also statements of opinion, *see In re Cognizant Tech. Solutions Corp. Sec. Litig.*, 2018 WL 3772675, at *25–26 (D.N.J. Aug. 8, 2018), and Plaintiff fails to allege falsity for the same reasons set forth above with respect to the other opinion statements.

III. The TAC Fails To Adequately Allege Loss Causation

Plaintiff must allege that "the defendant's fraud caused an economic loss." *Dura*, 544 U.S. at 338. To plead loss causation, "Plaintiff must allege 'that the subject of the fraudulent statement [] was the cause of the actual loss suffered, i.e., that the misstatement [] concealed something from the market that when disclosed, negatively affected the value of the security.'" *In re Tellium, Inc. Sec. Litig.*, 2005 WL 2090254, at *3 (D.N.J. Aug. 26, 2005) (quoting *Lentell v. Merrill Lynch*, 396 F.3d 161, 173 (2d Cir. 2005)). In short, Plaintiff must allege that his loss was caused by the market's discovery of Defendants' purported fraud. *Id.*

Plaintiff fails to plead that the market ever "discovered" any fraud by CorMedix. Plaintiff points to five "corrective disclosures" (¶ 289), except none is truly "corrective" of any prior statement. Plaintiff relies on (i) the March 1, 2021 disclosure of the First CRL; (ii) an April 14, 2021 press release reporting on the Company's recent meeting with FDA and guiding that it expected to resubmit the NDA in 3Q21; (iii) a May 13, 2021 press release announcing first quarter 2021 earnings and updating its expected timeline for the NDA resubmission to 4Q21; (iv) a September 7, 2021 press release withdrawing its prior guidance on the timeline for the NDA resubmission; and (v) the August 8, 2022 disclosure of the Second CRL.[26] In each case, Defendants disclosed new information about the FDA approval process; they did not correct prior statements or reveal a fraud. *See Dura*, 544 U.S. at 347 (loss causation not pled where plaintiff

[26] ¶¶ 219, 236, 242-46, 261, and 281.

alleged a stock drop following an announcement that "the FDA would not approve Dura's new asthmatic spray device" without pleading the required "causal connection"); *see also Pharmanet*, 720 F. Supp. 2d at 561 ("Plaintiff improperly relies on negative financial results after each of the quarterly public disclosures when there have been no allegations that the market recognized any of the alleged fraud[.]").

The TAC pleads that Plaintiff's loss was caused by corrective disclosures revealing a previously concealed fraud. ¶¶ 286-90. Nevertheless, any reliance on the "materialization of risk" theory is misplaced. Under this theory of loss causation, a plaintiff must plead that the materialization of an undisclosed risk caused its economic loss. *See McCabe v. Ernst & Young, LLP*, 494 F.3d 418, 429 (3d Cir. 2007). But here, if anything, it was the materialization of a *disclosed* risk that prompted a stock drop. Defendants' disclosures about the risks inherent in the FDA approval process, including risks relating to its third-party manufacturer and supplier, were extensive and specific. *Supra*, pp. 7–8; *see also supra*, Sec. II.A. In such circumstances, any reliance on the materialization of risk theory is misplaced. *See Rice Revocable Fam. Tr. 5/9/90 v. Intercept Pharms., Inc.*, 2022 WL 837114, at *23-24 (S.D.N.Y. Mar. 21, 2022) (failure to plead loss causation because the "broad risk that the [] NDA might not be approved on the merits of its application did materialize, and Intercept's stock dropped in response, but that risk was disclosed").

IV. The TAC Fails To Plead Scheme Liability

In order to plead scheme liability under Rule 10b-5(a) and (c), Plaintiff must allege, in addition to the elements of a Section 10(b) claim, that Defendants engaged in a "deceptive or manipulative act . . . *beyond* misstatements and omissions." *SEC v. Mintz*, 2024 WL 1173096, at *15 (D.N.J. Mar. 18, 2024) (emphasis in original). Here, however, the TAC rests entirely on alleged misstatements, and therefore fails to plead scheme liability. *See, e.g.*, ¶ 312.

V. The Section 20(a) Claim Against Individual Defendants Should Be Dismissed

Plaintiff's control person under Section 20(a) of the Exchange Act should be dismissed because Plaintiff cannot establish "a predicate violation" of Section 10(b) for all the reasons stated above. *Cal. Pub. Emps.' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 142 (3d Cir. 2004).

CONCLUSION

For the foregoing reasons, Defendants request that further leave to amend be denied and the Court dismiss the TAC with prejudice. Although leave to amend is generally permitted, ECF No. 91 at 2, "allowing leave to amend where there is a stark absence of any suggestion by the plaintiffs that they have developed any facts since the action was commenced, which would, if true, cure the defects in the pleadings under the heightened requirements of the PSLRA, would frustrate Congress's objective . . . of provid[ing] a filter at the earliest stage (the pleading stage) to screen out lawsuits that have no factual basis," *Chubb*, 394 F.3d at 164. That is the case here. The Court provided Plaintiff with an opportunity to buttress the SAC. *See* ECF No. 91. Yet, Plaintiff either abandoned certain claims (under the Securities Act) or doubled down on claims (under the Exchange Act) without pleading additional factual support. *Acito*, 47 F.3d at 55 (denying leave to amend based on failure to supplement allegations relating to failed FDA inspection). As then-Chief Judge Brown observed, "three bites at the apple is enough." *Intelligroup*, 527 F. Supp. 2d at 379 (denying leave to amend).

Dated: June 6, 2024

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Appendix A – True Statements Before First CRL

Date	True Statements Before First CRL	Alleged Speaker	TAC[1]
10/16/2019 and 11/14/2019	"***The FDA was supportive of Neutrolin's proposed manufacturing program,*** including the active pharmaceutical ingredients (API), the container closure and testing, and ***indicated that it will conduct a thorough review of all of the CMC information as well as assess the commercial readiness of the various manufacturing facilities at the time of NDA filing. No further CMC meetings with FDA are planned prior to NDA submission.***" [Press Releases]	CorMedix	¶¶ 178, 181
11/14/2019	"***As manufacturing experience expand[s], data on drug substance and drug product are generated and we s[ought] feedback from the FDA in quarter four to discuss the data that have been developed to support the NDA***. We believe that it is important to obtain guidance from FDA to ensure that we have all of the CMC information that the agency is expecting and can proactively address any question FDA may have. As we announced the press release on October 16, ***FDA provided guidance on the CorMedix CMC program and indicated data that will need to be available in the NDA for [its review]***." [Investor Call]	Phoebe Mounts	¶ 183
11/14/2019 11/14/2019	"As Phoebe [Mounts] has indicated, ***is important and critical for the NDA and depending on what is requested [CorMedix] needs to assure [it] completes the work in time to not [delay] the NDA filing***." "***FDA did request some additional data which we are working to complete, so we're optimistic that the CMC module we completed a[s] plan[ned] for filing with the FDA. FDA did indicate that it will conduct a thorough review of all of the CMC information as well as assess the commercial readiness of the various manufacturing facilities at the time of the NDA review. No further CMC meetings with FD[A] are planned prior to the NDA submission.***"	John Armstrong	¶¶ 184, 185

[1] All emphases in these Appendices mirror those in the TAC. According to the TAC, "the alleged false and/or misleading portions of the statements are both bolded and italicized." TAC, p. 75, n.104.

	"[T]he drug product manufacturer, that's [the vial] is in place and ***processes have been established and appropriate validation testing completed to enable manufacture of launch quantities***." [Investor Call]		
3/16/2020	"***Data provided by collaborators and others upon which we rely that has not been independently verified could turn out to be false, misleading, or incomplete.***" "We rely on third-party vendors, scientists, and collaborators to provide us with significant data and other information related to our projects, clinical trials, and business. ***If such third parties provide inaccurate, misleading, or incomplete data, our business, prospects, and results of operations could be materially adversely affected.***" "Our contract manufacturers ***may not be able to comply with the applicable FDA regulatory requirements, which could result in delays to our product development programs, could result in adverse regulatory actions against them or us, and could prevent us from ultimately receiving product marketing approval.***" "***If we and our contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with cGMP, we may experience manufacturing errors resulting in*** defective products that could be harmful to patients, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery, ***delay or prevention of filing or approval of marketing applications for our products***, cost overruns or other problems that could seriously harm our business. ***Not complying with FDA requirements could result in a product recall or prevent commercialization of our product candidates and delay our business development activities***. In addition***, such failure could be the basis for the FDA to issue a warning or untitled letter or take other regulatory or legal enforcement action, including*** recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, ***refusal to approve pending applications or supplemental applications***, and potentially civil and/or criminal penalties depending on the matter." [2019 10-K]	Khoso Baluch	¶¶ 190, 191; Ex. D at 32-33
7/8/2020	"***all of the modules for the Defencath™ New Drug Application [NDA] have been submitted*** to the [FDA]"; "***there has been ongoing dialogue with FDA as it reviews the submitted modules***" [Press Release]	CorMedix	¶ 198

7/8/2020	CorMedix was "very pleased to have ***completed the submission of the NDA, despite the limitations imposed by the COVID-19 pandemic, which delayed some required laboratory testing and our submission.***" [Press Release]	Khoso Baluch	¶ 199
8/10/2020	CorMedix had "***completed the rolling submission and review of the [NDA] for Defencath to the FDA*** for the prevention of … CRBSIs[] in patients undergoing hemodialysis via catheter." [Press Release]	CorMedix	¶ 201
8/10/2020	"We were pleased to announce ***the completion of our rolling submission for Defencath last month*** and look forward to providing updates on the acceptance for filing from FDA. . . . We also are ***making necessary preparations for the launch of Defencath in the U.S. hemodialysis market, following FDA approval***." [Press Release]	Khoso Baluch	¶ 202
8/10/2020	"[i]n March 2020, the Company began the modular submission process for the NDA for Defencath for the prevention of CRBSI in hemodialysis patients, and recently announced ***on July 8, 2020, that submission of all modules for the NDA was completed***" and that it "has not been informed of any delays by the FDA in the review of the NDA" [2Q20 10-Q]	Khoso Baluch	¶ 203
8/31/2020	"FDA had previously granted a ***rolling submission and review, which the Company completed at the end of June***." [Press Release]	CorMedix	¶ 206
8/31/2020	"we look forward to ***continuing to work together [with the FDA] expeditiously to complete the review of the Defencath NDA*** to address an unmet medical need." [Press Release]	Phoebe Mounts	¶ 207
11/5/2020	"***CorMedix continues its interactions with the FDA regarding the . . . NDA[] for Defencath*** for the prevention of . . . CRBSIs, in patients undergoing hemodialysis via central venous catheter." [Press Release]	CorMedix	¶ 209
11/5/2020	"In March 2020, we began the modular submission process for the NDA for Defencath for the prevention of CRBSI in hemodialysis patients, and ***recently announced on July 8, 2020, that submission of all modules for the NDA was completed***. In August 2020, the FDA accepted for filing the Defencath NDA… ***The FDA noted that*** . . . ***it had not identified any potential review issues at this time.***" [10-Q]	Khoso Baluch	¶ 211

11/18/2020	"CorMedix has been notified that ***based on the [FDA]'s ongoing dialogue with the Company, discussion at an advisory committee is not needed, and it will continue to work on the application with CorMedix during the remainder of the review cycle***." [Press Release]	CorMedix	¶ 214
11/18/2020	"[w]e are very happy with ***the level of engagement between FDA and the CorMedix team during the NDA review process***" [Press Release]	Khoso Baluch	¶ 215
11/18/2020	"It is gratifying that the ***tremendous effort of the CorMedix team has resulted in continuing progress with the FDA in the review of the NDA*** and that the decision was made that ***no discussion with an advisory committee is needed***. We intend to ***continue our effort and dialogue with the Agency to ensure that the priority review process can be completed expeditiously*** to address the unmet medical need . . . ." [Press Release]	Phoebe Mounts	¶ 216

Appendix B – True Statements After First CRL

Date	True Statements After First CRL	Alleged Speaker	TAC
3/9/2021	"Additionally, a related approvability issue with the FDA's request communicated directly to CorMedix for a required ***manual extraction study to demonstrate that the labeled volume of the drug product can be consistently withdrawn from vials.***" "***We are working with the CMO to provide existing documentation to demonstrate that corrective actions are adequate to assure production controls are in place and to ensure standard operating procedures are consistent with actual practices and documentation is completed in a timely manner.***" [Investor Call]	Phoebe Mounts	¶¶ 223
3/9/2021	"***All drug product made at the CMO for validation batches and subsequent batches met specifications. The drug product*** was put on accelerated and normal stability testing and continues to meet specifications." Question from analyst: "And then, just in terms of your overfill margins, is there anything you're doing different here? Or anything different to industry standard in terms of your overfill margins?" "***We are following the guidelines that are given, and we are following the guidelines on the overfill. And it's not different than we were doing before. We are within the guidelines.***" [Investor Call]	John Armstrong	¶¶ 224, 227
3/16/2021	"***We are working with the manufacturing facility to develop plans for resolution of the deficiencies***. Additionally, the FDA is requiring ***a manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from the vials despite an existing in-process control to demonstrate fill volume within specifications***." [10-K]	Khoso Baluch and Matthew David	¶ 230
3/30/2021	"FDA noted concerns at the third-party manufacturing facility after a review of records requested by FDA and provided by the manufacturing facility, and has requested a ***manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from vials.***" "***CorMedix continues to work closely with our third-party manufacturing facility*** and	CorMedix	¶ 229

	is planning for a meeting with the FDA in mid-April to obtain agreement on the adequacy of our proposed plans for resolution of the deficiencies." [Press Release]		
3/30/2021	"***We have been working intensely with our third-party manufacturing facility to develop the proposed resolutions to the deficiencies. There has been a strong collaborative effort to develop responses for each of the six deficiencies identified by FDA for the manufacturing facility. In addition, we have developed the protocol for the manual extraction study being required by FDA to demonstrate that the labeled volume of the drug product can be consistently withdrawn from vials.***" Question from analyst: "Obviously, you said the goal of the meeting is to gain alignment with FDA on the resolution plans. But just wondering if you will actually have any of the work requested by FDA completed by the meeting, either in terms of documentation protocols, or the vial fill volume study or air flow visualization studies that they asked for, will you've actually completed any, or have any new data to take to the meeting?" "So, yes, we obviously were involved in developing the propose response. Some of those proposed responses involved existing documentation. And ***we make[1] sure that - where we could, we provided information that was responsive to the deficiency***. So, ***there is new information there for them to review for some of the responses***." [Investor Call]	Phoebe Mounts	¶¶ 233, 234; Ex. V at PDF p.6
4/14/2021	"***CorMedix and the CMO are currently evaluating available data to determine if additional process qualification will be needed with subsequent validation to address these issues.***" "***CorMedix and the CMO continue to work closely to ensure that the identified deficiencies are resolved*** prior to resubmission of the DefenCath NDA. ***CorMedix will provide updates on the timeline as resolution of the deficiencies proceeds***." [Press Release]	CorMedix	¶ 239
4/14/2021	"Manufacturing Overview: Supply Chain Substantially Completed; Launch Quantities in Production[.] ***Successfully concluded technical transfer and validation of the drug product manufacturing process***, which has enabled production at 2 different manufacturing locations"	CorMedix	¶ 240

[1] The TAC incorrectly alters the quotation as "ma[d]e." ¶ 234 (alteration in TAC).

	"***[l]aunch quantities are already in production***" [Corporate Presentation]		
5/13/2021	"***CorMedix successfully completed the agreed upon protocol for the manual extraction study identified in the Complete Response Letter*** that FDA is requiring ***as confirmation of in-process controls to demonstrate that the labeled volume can be consistently withdrawn from the vials***." [Press Release]	CorMedix	¶ 249
5/13/2021	"As we previously discussed, the [] CRL, sent to CorMedix by the FDA required ***a manual extraction study to demonstrate that the labeled volume of DEFENCATH can be consistently withdrawn from the vials to confirm the manufacturing in process controls.***" "***The CorMedix CMC and regulatory teams continue to focus our efforts on resolving the deficiencies [sent] to the [] CMO***, in the post application action letter." [Investor Call]	Phoebe Mounts	¶ 252
5/13/2021	"***[t]he Company and the CMO continue to work closely to ensure that the identified deficiencies are resolved*** prior to resubmission of the DefenCath NDA" [10-Q]	Khoso Baluch	¶ 253
8/12/2021	"We are also balancing our preparation for launching DEFENCATH while limiting our cash burn so that ***financially we have the resources required to efficiently bring DEFENCATH to patients in the U.S. market when FDA approval is received.***" "We are carefully balancing our cash burn, while preparing for the launch of DEFENCATH ***once we have approval of the NDA by the FDA***." [Investor Call]	Khoso Baluch	¶ 257
8/12/2021	"As I have explained previously, we have ***successfully completed the manual extraction study required by FDA*** and the [] CRL sent by the FDA to CorMedix. ***We have demonstrated that the labeled volume of DEFENCATH can be consistently withdrawn from the v[ials].***" "The process qualification and validation are done by the manufacturing facility and ***we are working closely with them and CMC consultants engaged by CorMedix to ensure that we are addressing FDA concerns appropriately***. The deficiencies communicated to the CMO by FDA need to be satisfactorily addressed for approval of the DEFENCATH NDA."	Phoebe Mounts	¶¶ 258, 259

	"***We have an abundance of data on stability of other batches that have been produced. And so we expect to be able to show consistency.***" [Investor Call]		
3/30/2022	"***[w]e are committed to providing updates to investors as appropriate*** over the coming months during the review process" "it is important to anticipate ***potential supply chain challenges*** and ensure multiple sources are in place to provide adequate inventory" [Investor Call]	Phoebe Mounts	¶¶ 270, 272
5/12/2022	"***any FDA inspection of our CMO will assess the commercial readiness of the facility and manufacturing operations beyond those specific to DefenCath***" "from a supply chain standpoint, ***we're also continuing initiatives to dual source key components and active ingredients in order to de-risk*** potential global supply chain disruptions as well as ***potential governmental regulatory actions at any key supplier***" "On the launch prep side, when – ***in terms of activities that we are currently undertaking, we are doing right now all the typical prelaunch planning***." [Investor Call]	Joe Todisco	¶¶ 274, 276, 277; Ex. X at PDF p.4, 9
6/15/2022	"***[T]he big obstacle does appear to be the FDA's inspection at the site***." "I think that one of the key variables, though, is that ***this is an inspection of facility that is larger than just the manufacturing operations related to DefenCath.***" [JMP Conference]	Joe Todisco	¶ 279

Appendix C – Non-Actionable Forward-Looking Statements

Date	Non-Actionable Forward-Looking Statements	Alleged Speaker	TAC
10/16/2019	"[w]e anticipate that ***Neutrolin can be approved in the second half of 2020*** and we intend to launch Neutrolin commercially in the US promptly after its approval either by ourselves or with a partner" [Press Release]	Khoso Baluch	¶ 179
2/3/2020	"***CorMedix remains on schedule for a potential NDA approval during the second half of 2020.***" [Press Release]	CorMedix	¶ 187
4/22/2020	"[w]e ***have remained on schedule towards an anticipated approval in the second half of 2020***, subject of course to possible delays at FDA due to the coronavirus pandemic" [Press Release]	Khoso Baluch	¶ 194
5/11/2020	"[we] have been working remotely since mid-March, a transition we have made with little disruption and as a result ***we are maintaining our guidance for an anticipated decision on approval of the NDA in the second half of 2020***." [Press Release]	Khoso Baluch	¶ 196
3/9/2021	"***Based on our discussions with the CMO, we believe these deficiencies can be resolved in the coming weeks***." "***We have submitted data to FDA to demonstrate performance with the specifications but we intend to conduct the requested manual extraction study and expect it to be completed in the next several weeks***. Another deficiency identifies concerns an airflow visualization study, and ***will likely necessitate repeating the study to demonstrate adequate dynamic conditions*** in the study, ***which we believe can be accomplished in the next several weeks***." [Investor Call]	Phoebe Mounts	¶ 223
5/13/2021	"As a result, ***our current plan is to be able to resubmit the [DEFENCATH] NDA in [4Q21]***." [Investor Call]	Phoebe Mounts	¶ 243

8/12/2021	"CorMedix remains focused in its efforts to resolve the deficiencies sent to the third-party manufacturer in the Post-Application Action Letter and ***remains on schedule to re-submit the DefenCath™ New Drug Application in [4Q21]***." [Press Release]	CorMedix	¶ 256
8/12/2021	"The work has continued and we are reiterating that ***at present, we are on schedule to be able to resubmit the CorMedix NDA in quarter 4, 2021.***" "To summarize, ***we continue to focus our effort expeditiously resolving the third-party manufacturing deficiencies with a plan to resubmit in quarter 4, 2021.***" [Investor Call]	Khoso Baluch	¶ 257
8/12/2021	"I will start by assuring you that ***we remain on schedule to resubmit the new drug application or NDA in [4Q21]***." "***The CMC and regulatory teams of CorMedix are working collaboratively with the CMO to ensure the generation of the required data and documentation to resubmit the NDA in [4Q21]***." [Investor Call]	Phoebe Mounts	¶ 258

Appendix D – Opinion Statements and Non-Actionable Statements of Corporate Optimism

Date	Opinion Statements and Non-Actionable Statements of Corporate Optimism	Alleged Speaker	TAC
11/14/2019	"As mentioned previously, ***I have working with me a very experienced and competent team, they have the needed breadth and depth in the requirements for sourcing, manufacturing, distribution and quality assurance that is necessary for both the US and foreign markets.***" [Investor Call]	John Armstrong	¶ 185
3/16/2020	"to my knowledge: [t]he [2019 10-K] fully complies with the requirements of Section 13(a) or 15(d) of the [Exchange Act]; and ***[t]he information contained in the [2019 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company.***" [10-K]	Khoso Baluch Matthew David	¶ 192; Ex. U; *see also* ¶¶ 204, 212, 231, 254
8/10/2020	"[w]e believe ***we have the team***, the focus, and a therapy that will meaningfully improve patient outcomes and are excited about the opportunities in front of us" [Press Release]	Khoso Baluch	¶ 202
11/5/2020	"[w]e believe ***we have the team***, the focus, the resources, and a novel catheter lock solution that will meaningfully improve patient outcomes and are excited about the opportunities in front of us" [Press Release]	Khoso Baluch	¶ 210
3/9/2021	"We believe ***we have within CorMedix and the CMO, the resources and capabilities to achieve successful resolution of the manufacturing deficiencies to the satisfaction of the FDA***." [Investor Call]	Khoso Baluch	¶ 225
3/30/2021	"we remain confident that ***we have the right team and appropriate resources in place to resolve the third-party manufacturing deficiencies that have been identified***" [Investor Call]	Khoso Baluch	¶ 232
5/13/2021	"[w]e believe ***we have the right team and resources to accomplish this as we advance DefenCath through the regulatory approval process***"	Khoso Baluch	¶¶ 250, 251

	"[w]e remain confident that ***we have the right team and appropriate resources in place to resolve the third-party manufacturing deficiency***" [Press Release]		
8/12/2021	"We remain confident that ***we have the right team and appropriate resources in place to resolve the third-party manufacturing deficiencies that have been identified***" [Investor Call]	Khoso Baluch	¶ 257
2/28/2022	"We believe that ***we and the manufacturer have adequately addressed the concerns the Agency identified in the CRL and PAAL***." [Press Release]	Phoebe Mounts	¶ 266; Ex. G at 2
3/28/2022	"We believe that ***both CorMedix and our contract manufacturer have adequately addressed the concerns the Agency identified during the review of the original NDA***" [Press Release]	Phoebe Mounts	¶ 267; Ex. H at 2
3/30/2022	"We believe that ***CorMedix and the manufacturer have adequately addressed the concerns identified by FDA***" [Investor Call]	Phoebe Mounts	¶ 268; Ex. W at PDF p.4
6/15/2022	"I think ***they're going to take all care to work diligently through any observations and work with the FDA on, if necessary, improving any compliance concerns FDA could raise.***" "***So from everything that we can see***, I'm optimistic that everything is moving in the right direction." [JMP Conference]	Joe Todisco	¶ 279